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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/541,624	07/06/2005	Joerg Sabczynski	PHDE030003US	8349

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EXAMINER

BOR, HELENE CATHERINE

ART UNIT	PAPER NUMBER
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3768

MAIL DATE	DELIVERY MODE
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10/09/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/541,624	Applicant(s) SABCZYNSKI ET AL.	
	Examiner Helene Bor	Art Unit 3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 July 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 July 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The examiner recognizes the applicant's newly amended claims 1, 11, 13 – 15. Under examination are the newly amended, previously amended and previously submitted claims, 1 – 16.

Response to Arguments

1. Applicant's corrections filed 07/17/2007 in response to the claim objections overcome the claim objections and the examiner withdraws all claim objections.
2. Applicant's arguments filed 07/17/2007 have been fully considered but they are not persuasive. Applicant argues that Strommer'375 does not teach using only 2-D imagery when tracking an instrument being inserted into the body of a patient. The examiner respectfully disagrees as Strommer'375 teaches that the system can be adapted for a two-dimensional environment (Page 3, Para 0036). Thus, the rejection of claims 1 – 16 is maintained.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claim 1-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Strommer'375 (US Patent No. 2002/0049375 A1).

Claim 1: Strommer'375 teaches a method of tracking an instrument that is inserted into the body of a patient (abstract) using only 2-D imagery (Page 3, Para

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0036). Strommer'375 also teaches the procedure of detecting an organ timing signal [movement signal] of the inspected organ, detecting a plurality of two-dimensional images of the inspected organ using an image detector, and detecting the location and orientation of the image detector (Page 3, Para 0033). Strommer'375 teaches displaying an image sequence of a moving inspected organ and each image in the image sequence is associated with the location and the orientation of the image within a predetermined coordinate system (Page 3, Para 0036). Strommer'375 further teaches selecting one of the previously stored two-dimensional images according to a real-time reading of the organ timing signal and displaying the selected two-dimensional image (Page 3, Para 0036). Strommer'375 teaches a method detecting a real time two-dimensional image of the inspected organ, detecting the location and orientation of the image detector, and detecting the location and orientation of the surgical tool (Page 4, Para 0043).

Claim 2/1: Strommer'375 teaches a method wherein an electrocardiogram detected the movement signal (Figure 12, Element 406). Strommer'375 also teaches using a respiratory rate monitor (Page 10, Para 0149).

Claim 3/1: Strommer'375 teaches a method wherein the position of the instrument is represented superimposed [superposed] on the selected 2D images (Page 4, Para 41).

Claim 4/1: Strommer'375 teaches 2D images from a single movement phase are available for selection from the image database (Page 18, Para 0245).

Claim 5/1: Strommer'375 teaches a method steps b & c - e are carried out a number of times (Page 7, 0110-0111) and in varying order (Figure 10 & Figure 22).

Claim 6/1: Strommer'375 teaches a method wherein the image database contains 2D images from various projection directions (Page 7, Para 0110-0111 & Page 8, Para 0119).

Claim 7/1: Strommer'375 teaches a method wherein the 2D images are generated by means of X-radiation and/or ultrasound (Figure 12, Element 404 & Page 7, Para 0101).

Claim 8/1: Strommer'375 teaches a method wherein a sensor [reference probe] is mounted on the image detector of the two-dimensional image acquisition system (Page 6, Para 0093). Strommer'375 further teaches that the image acquisition system consists of a two-dimensional image acquisition device (Page 7, 0100) wherein the two-dimensional image acquisition device can be of any type known in the art, such as an x-ray (Page 7, Para 0101).

Claim 9/1: Strommer'375 teaches a method wherein at least one sensor [reference probe] is arranged on or in the body of the patient (Page 6, Para 0093).

Claim 10/1: Strommer'375 teaches a method wherein the organ timing signal [breathing movement (Page 10, Para 0149)] is compensated for using pre-stored images [models] of the body (Page 3, Para 0032). Strommer'375 teaches that cyclic organs, such as an artery, constantly moves and that prior art were substantially inaccurate in representing information (Page 2, Para 0026).

Claim 11: Strommer'375 teaches an arrangement for tracking an instrument that is inserted into the body of a patient (abstract) using only 2-D imagery (Page 3, Para 0036). Strommer'375 teaches a device for generating 2D images of a body volume of interest (Figure 12, Element 418 & 404). Strommer'375 teaches a unit for determining set imaging parameters of the device (Figure 12, Element 408 & 402). Strommer'375 teaches a signal measurement unit for detecting a movement signal which represents movement phases of a periodic internal movement of the body (Figure 12, Element 406). Strommer'375 teaches a storage unit for storing an image database of 2D images of the body volume together with the associated imaging parameters and the associated movement phases (Figure 12, Element 414). Strommer'375 teaches a position measurement unit for determining the spatial position of the instrument that is inserted into the body (Figure 12, Element 408, 432_N, 432₁, & 432₂). Strommer'375 teaches a control and computation unit for selecting at least one 2D image from the image database, which 2D image corresponds in terms of its associated movement phase to the movement phase belonging to the spatial position of the instrument, and for determining the position of the instrument on the selected 2D image (Figure 12, Element 402).

Claim 12/11: Strommer'375 teaches an arrangement wherein it is designed for carrying out a method as claimed 1 (Figure 12).

Claim 13: Strommer'375 teaches a real-time imaging system for tracking an instrument that is inserted into the body of a patient using only 2-D imagery (Figure 16A, Element 484, Abstract & Page 3, Para 0036). Strommer'375 teaches the real-time

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imaging system is located outside of the patient either above or below and is a fluoroscopic or ultrasound system (Page 16, Para 0227). Strommer'375 teaches an instrument tracking system that is capable of generating and storing 2D images of a volume of interest in a body (Figure 12, Element 50) prior to insertion of an instrument into the body. It has been held that the recitation that an element is "capable of" performing a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense, *In re Hutchison* 69 USPQ 138. Strommer'375 also teaches an instrument tracking system for detecting an organ timing signal [movement signal] of the inspected organ, detecting a plurality of two-dimensional images of the inspected organ using an image detector, and detecting the location and orientation of the image detector (Page 3, Para 0033). Strommer'375 teaches displaying an image sequence of a moving inspected organ and each image in the image sequence is associated with the location and the orientation of the image within a predetermined coordinate system (Page 3, Para 0036). Strommer'375 further teaches selecting one of the previously stored two-dimensional images according to a real-time reading of the organ timing signal and displaying the selected two-dimensional image (Page 3, Para 0036). Strommer'375 teaches a means for tracking the position of the instrument upon insertion into the body (Figure 12, Element 408). Strommer'375 teaches a means for superimposing the position of the instrument with the selected, stored 2D image (Figure 12, Element 416).

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Claim 14/13: Strommer'375 teaches an instrument tracking system wherein the periodic internal movement of the body is caused by the cardiac system (Page 6, Para 0094 & Page 10, Para 0149).

Claim 15/13: Strommer'375 teaches an instrument tracking system wherein the periodic internal movement of the body is caused by the respiratory system (Page 6, Para 0094 & Page 10, Para 0149).

Claim 16/13: Strommer'375 teaches an instrument tracking system wherein the means for measuring organ timing signal [movement phases] includes an electrocardiogram (Figure 12, Element 406 & Figure 18, Element 632).

Claim 17/13: Strommer'375 teaches an instrument tracking system comprising at least one reference probe positioned on at least one of the means for generating 2D images and the body (Page 6, Para 0093 & Figure 12, Element 420).

Conclusion

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Helene Bor whose telephone number is 571-272-2947. The examiner can normally be reached on M-F 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni Mantis-Mercader can be reached on 571-272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

hcb


ELENI MANTIS MERCADER
SUPERVISORY PATENT EXAMINER